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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,019	09/25/2003	Jing Yang	CEN 5014 USNP	2644

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Restriction required
5-28-05
F-10-28-05

Faxed to KDon 5/3/05

PTO-90C (Rev. 10/03)

Office Action Summary

Application No.	Applicant(s)
10/671,019	YANG ET AL.
Examiner	**Art Unit**
Rosanne Kosson	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (5) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 24 September 2003.

2a)☐ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 8 and 17, drawn to a polypeptide having at least 80% sequence identity to one of SEQ ID NOS: 2-16, and a method of generating antibodies to Gas6, comprising immunization with the polypeptide, classified in class 530, subclass 300 or 350.

II. Claims 5-7, drawn to a recombinant DNA molecule encoding one of the polypeptides of SEQ ID NOS: 2-16, and a vector and a host cell comprising the DNA molecule, classified in class 435, subclass 325.

III. Claim 8, drawn to a method of generating antibodies to Gas6, comprising immunization with a polypeptide having at least 80% sequence identity to one of SEQ ID NOS: 2-16, classified in class 514, subclass 12.

IV. Claim 9, drawn to a method of generating antibodies to Gas6, comprising immunization with a vector comprising a DNA sequence encoding one polypeptide of SEQ ID NOS: 2-16, classified in class 514, subclass 44.

V. Claim 10, drawn to a method of screening recombinant antibodies with a polypeptide having the sequence of one of SEQ ID NOS: 2-16, classified in class 435, subclass 7.1.

VI. Claims 11-16, drawn to an antibody to one polypeptide of SEQ ID NOS: 2-16, or an antigen-binding fragment thereof, classified in class 530, subclass 387.1.

VII. Claims 18 and 19, drawn to a method of detecting a Gas6 polypeptide in a sample, comprising the use of an antibody to one polypeptide of SEQ ID NOS: 2-16, classified in class 435, subclass 7.1.

VIII. Claim 20, drawn to a method of preventing or treating cardiovascular or other disease, comprising the use of an antibody to one polypeptide of SEQ ID NOS: 2-16, classified in class 424, subclass 130.1.

IX. Claim 20, drawn to a method of preventing or treating cardiovascular or other disease, comprising the use of an polypeptide of one of SEQ ID NOS: 2-16, classified in class 514, subclass 12.

X. Claims 21, 25, 26 and 32, drawn to a Gas6 antibody comprising at least one variable region comprising at least one heavy chain of SEQ ID NO: 26 and at least one light chain of SEQ ID NO: 28, classified in class 530, subclass 387.1.

XI. Claims 22, 25, 26 and 32, drawn to a Gas6 antibody comprising at least two heavy chain CDRs having the amino acid sequence of one or two of SEQ ID NOS: 29-31, or comprising at least two light chain CDRs having the amino acid sequence of one or two of SEQ ID NOS: 32-34, classified in class 530, subclass 387.1.

XII. Claim 23, drawn to a Gas6 antibody comprising at least one heavy chain CDR having the amino acid sequence of one of SEQ ID NOS: 29-31, or comprising at least one light chain CDR having the amino acid sequence of one of SEQ ID NOS: 32-34; claim 24, drawn to a Gas6 antibody that binds to the same polypeptide as an antibody comprising one heavy chain CDR or one light chain CDR having the amino acid sequence of one of SEQ ID NOS: 29-34; and claims 25, 26 and 32, classified in class 530, subclass 387.1.

XIII. Claims 27-31, drawn to an isolated nucleic acid molecule encoding one of:

a) the polypeptide sequence for a Gas6 antibody comprising at least one variable region comprising at least one heavy chain of SEQ ID NO: 26 and at least one light chain of SEQ ID NO: 28, or

b) the polypeptide sequence for a Gas6 antibody comprising at least two heavy chain CDRs having the amino acid sequence of one or two of SEQ ID NOS: 29-31, or comprising at least two light chain CDRs having the amino acid sequence of one or two of SEQ ID NOS: 32-34, or

c) the polypeptide sequence for a Gas6 antibody comprising at least one heavy chain CDR having the amino acid sequence of one of SEQ ID NOS: 29-31, or comprising at least one light chain CDR having the amino acid sequence of one of SEQ ID NOS: 32-34, or the polypeptide sequence for a Gas6 antibody that binds to the same polypeptide as an antibody comprising one heavy chain CDR or one light chain CDR having the amino acid sequence of one of SEQ ID NOS: 29-34, classified in class 536, subclass 23.5.

Upon election of one of Groups I-IX, Applicants must choose **ONE** polypeptide SEQ ID NO. from among SEQ ID NOS: 2-16, as each SEQ ID NO. is a distinct invention requiring separate searches. These are NOT species. The polypeptides of SEQ ID NOS: 2-16 are structurally distinct molecules and function to produce at least 15 structurally distinct antibodies. Therefore, the polypeptides of SEQ ID NOS: 2-16 are patentably distinct.

Upon election of Group XI, if Applicants choose heavy chain CDRs, Applicants must choose the one or two SEQ ID NOS. from which the heavy chain CDRs are derived- **ONE** if the CDRs are derived from the same polypeptide and **TWO** if the CDRs are derived from different polypeptides. Similarly, if Applicants choose light chain CDRs, Applicants must choose the one or two SEQ ID NOS. from which the light chain CDRs are derived- **ONE** if the CDRs are derived from the same polypeptide and **TWO** if the CDRs are derived from different polypeptides. This is not a species election, as each polypeptide sequence is patentably distinct.

Upon election of Group XII, if Applicants choose a heavy chain CDR, Applicants must choose **ONE** SEQ ID NO. from which the heavy chain CDR is derived. Similarly, if Applicants choose a light chain CDR, Applicants must choose **ONE** SEQ ID NO. from which the light chain CDR is derived. This is not a species election, as each polypeptide sequence is patentably distinct.

Upon election of Group XIII, Applicants must choose **ONE** of a) or b) or c). If b) is chosen, Applicants must choose either heavy chain or light chain CDRs. If heavy chain CDRs are chosen, Applicants must choose the one or two SEQ ID NOS. from which the heavy chain CDRs are

derived- ONE if the CDRs are derived from the same polypeptide and TWO if the CDRs are derived from different polypeptides. Similarly, if light chain CDRs are chosen, Applicants must choose the one or two SEQ ID NOS. from which the light chain CDRs are derived- ONE if the CDRs are derived from the same polypeptide and TWO if the CDRs are derived from different polypeptides. This is not a species election, as each polypeptide sequence is patentably distinct. If c) is chosen, Applicants must choose either a heavy chain or a light chain CDR. If a heavy chain CDR is chosen, Applicants must choose ONE SEQ ID NO. from which the heavy chain CDR is derived. Similarly, if a light chain CDR is chosen, Applicants must choose ONE SEQ ID NO. from which the light chain CDR is derived. This is not a species election, as each polypeptide sequence is patentably distinct.

Applicants should note that searching each polypeptide or polynucleotide sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid sequence or nucleotide sequence, and each result set from a particular database must be carefully considered. Hence, the search for even two different polypeptides or polynucleotides, and different polypeptide and polynucleotide segments in the databases, in addition to searching the organic molecule databases, would require extensive searching and review.

The inventions are distinct, each from the other because of the following reasons.

The polypeptides of Group I are related to the DNA molecules of Group II by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, as the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, these inventions are patentably distinct.

The polypeptide Group I is related to the antibodies of Groups VI and X-XII by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in other, materially different processes from the

production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify a natural ligand of the protein. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions. Therefore, these inventions are patentably distinct.

The inventions of Groups I and XIII are related, as the DNA molecule of Group XIII encodes an antibody that binds to the polypeptide of Group I. But, the polypeptide is not needed for production of the antibody, and these products are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The inventions of Groups I and III are related as the method of Group III comprises immunization with a polypeptide of Group I. But, the polypeptides of Group I may be used in a materially different process, e.g., as pharmaceutical compositions that may be administered. Thus, notwithstanding the relationship, the two inventions are patentably distinct.

The inventions of Groups I and IV are related as the method of Group IV comprises immunization with a vector that comprises a DNA sequence that encodes a polypeptide of Group I. Clearly, the polypeptide is not required for the practice of the immunization method, nor are the polypeptide and the immunization composition disclosed as capable of use together. Thus, notwithstanding the relationship, the two inventions are patentably distinct.

The inventions of Groups I and V are related, as the polypeptide of Group I may be used in the screening method of Group V. But the polypeptide of Group I may be used in a materially different process of using that product, such as for the production of antibodies or as a pharmaceutical composition. Therefore, these inventions are patentably distinct.

The polypeptide of Group I is related to the detection method of Group VII, as it binds to the antibody of Group VII. But the polypeptide of Group I may be used in a materially different process

of using that product, such as for the production or purification of antibodies or as a pharmaceutical composition. Therefore, these inventions are patentably distinct.

The inventions of Groups I and VIII are related, as the polypeptide of Group I binds to the antibody used in the medical treatment method of Group VIII. But the polypeptide of Group I may be used in a materially different process of using that product, such as for the production or purification of antibodies or as a pharmaceutical composition itself. Therefore, these inventions are patentably distinct.

The inventions of Groups I and IX are related, as the polypeptide of Group I may be used in the medical treatment method of Group IX. But the polypeptide of Group I may be used in a materially different process of using that product, such as for the production or purification of antibodies. Therefore, these inventions are patentably distinct.

The DNA molecules of Group II are related to Group III, as these DNA molecules encode a polypeptide that is used in the method of Group III. But, these DNA molecules are not required for practicing this methods, and these groups are not disclosed as capable of use together. Thus, these inventions are patentably distinct.

The DNA molecules of Group II are related to Groups IV, V, VII and VIII, methods of making and using antibodies to the polypeptides of Group I, as the antibodies in these methods bind to polypeptides encoded by the DNA molecules of Group II. The DNA molecules of Group II are related to Group IX, a method of using the polypeptides of Group I, as the polypeptides in this method are encoded by the DNA molecules of Group II. But, these DNA molecules are not required for practicing these methods, and the DNA molecules and these methods are not disclosed as capable of use together. Thus, notwithstanding the relationship, these inventions are patentably distinct.

The DNA molecules of Group II are related to the antibody molecules of Group VI, as the encode the polypeptide that binds to these antibodies. But, the DNA molecules are not necessary for production of the antibody, and the two Groups are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The DNA molecules of Group II are related to Groups X-XII, as the protein that is encoded by the DNA and necessary for the production of the antibody. However, the DNA itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The DNA molecules of Group II are related to Group XIII, as the DNA of Group II encodes the protein that binds to the antibody encoded by the DNA molecules of Group XII. However, the DNA molecules of Group II are not necessary for antibody production, and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The methods of Groups III, IV, V, VII, VIII and IX are unrelated- a method of generating antibodies by immunization with a polypeptide, a method of generating antibodies by immunization with an expression vector, a method of screening antibodies, a method of detecting a polypeptide, a method of treating cardiovascular or any other disease with an antibody, and a method of treating cardiovascular or any other disease with a polypeptide. These methods are not disclosed as capable of use together, and they have different modes of operation, different functions, or different effects. Therefore, these inventions are patentably distinct.

The antibodies in each of Groups VI, X, XI and XII are different products because each one comprises a different polypeptide sequence. These polypeptide sequences are structurally and functionally distinct. Thus, each of these inventions is patentably distinct.

The antibodies in each of Groups VI, X, XI and XII and the DNA molecules of Group XIII are related by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the

recombinant production of the protein in a host cell. Although the DNA and the protein are related, they are distinct inventions because the protein product can be made by other and materially distinct processes, such immunization with the polypeptides to which the antibodies bind. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, these inventions are patentably distinct.

The antibodies in each of Groups VI, X, XI and XII and the methods of Groups IV, V and IX are unrelated- a method of generating antibodies using DNA encoding an antigenic polypeptide), a method of screening antibodies, and a method of treating cardiovascular or any other disease with a polypeptide. These methods are not disclosed as capable of use together, and they have different modes of operation, different functions, and different effects. Therefore, these inventions are patentably distinct.

The antibodies of Groups IX, X and XI and the methods of Groups VI and VII are unrelated- a method of detecting a polypeptide, and a method of treating cardiovascular or any other disease with an antibody, because antibodies other than those of Groups IX, X and XI are used. These methods are not disclosed as capable of use together, and they have different modes of operation, different functions, and different effects. Therefore, these inventions are patentably distinct.

The method of Group III and the antibodies of Groups VI are related as a process of making Gas6 antibodies and Gas6 antibodies. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process. In the instant case, the antibodies may be made as monoclonal antibodies, i.e., by culturing and screening hybridomas. They need not be antibodies produced by immunization with polypeptides. Therefore, these inventions are distinct.

The method of Group III and the antibodies in each of Groups X, XI and XII are related as a method of making antibodies and antibodies with known polypeptide sequences. The antibodies generated in the method of Group III need not have the polypeptides sequences of the molecules of Groups X-XII. Thus, these molecules have different structures, and these inventions are, therefore, patentably distinct.

The method of Group III and the DNA molecules of Group XIII are related, as the DNA molecules of Group XIII encode antibodies that bind to Gas6 polypeptides, while the method of Group III is method for generating antibodies by immunization. The DNA molecules of Group XIII are not required for the method of Group III. The method of Group III may generate antibodies not encoded by the DNA molecules of Group XIII. Therefore, these inventions are distinct.

The antibodies of Group VI and the method of Group VII are related, as an antibody of Group VI may be used in the method of Group VII. But, an antibody of Group VI may be used in other, materially different processes, such as in a pharmaceutical composition in its own right, or to purify the polypeptide to which it binds. Therefore, these inventions are distinct.

The antibodies of Group VI and the method of Group VIII are related, as an antibody of Group VI may be used in the method of Group VIII. But, an antibody of Group VI may be used in other, materially different processes, such as assaying or purifying the polypeptide to which it binds. Therefore, these inventions are distinct.

The DNA molecules of Group XII and the methods of Groups III, IV, VI, VII and VIII are unrelated- a method of generating antibodies (using DNA encoding an antigenic polypeptide), a method of screening antibodies, a method of detecting a polypeptide, a method of treating cardiovascular or any other disease with an antibody, and a method of treating cardiovascular or any other disease with a polypeptide. These methods are not disclosed as capable of use together,

and they have different modes of operation, different functions, and different effects. Therefore, these inventions are patentably distinct.

Additionally, the search for any one group is not required for the eleven other groups, thereby creating an undue burden of search and examination. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Further, the different groups have each acquired a separate status in the art, as shown in part by their different classifications. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2005-04-18

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653